

file copy

Interview Summary	Application No.	Applicant(s)	
	09/533,906	COLLINS ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Diana Johannsen. (3) ____.
- (2) Jean Fordis. (4) ____.

Date of Interview: 06 May 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: ____.

Claim(s) discussed: NA.

Identification of prior art discussed: Feix et al; Pollet et al.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

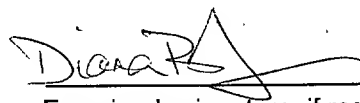
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Attachment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

- i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

 5/6/02
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135 (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Attachment to Interview Summary

On 4/18/02, 4/22/02, 4/23/02, 4/24/02, and 4/25/02, the status of the Notice of Allowability was briefly discussed. Arrangements were made for pick up of the Notice of Allowability by applicants' representatives (in lieu of mailing), as agreed to on 4/15/02 (see the Interview Summary of paper no. 36). The Notice of Allowability and accompanying papers were picked up on 4/25/02.

On 4/25/02, Ms. Fordis contacted the examiner to request clarification of two statements in the Attachment to the Notice of Allowability (see discussion below).

These two issues were briefly discussed on 4/29/02, and it was agreed that the examiner would retrieve the application file, review the relevant portions of the Attachment, and contact Ms. Fordis. These issues were discussed in a telephone interview on 5/6/02.

First, Ms. Fordis had noted that in paragraph 5 of the Attachment, the examiner had incorrectly indicated applicant's priority date as December 12, 1987, whereas the correct date is December 21, 1987. The examiner indicated that the recitation of "December 12" was a typographical error, and confirmed that she had intended to indicate the date of "December 21, 1987."

Second, Ms. Fordis noted that the examiner's statement in paragraph 6(a) at pages 4-5 appeared to be inconsistent with statements made in the Interview Summary of paper no. 35 with respect to the Feix et al and Pollet et al references. Ms. Fordis noted that the Interview Summary stated that the "claims do not encompass methods that require additional steps of target preparation prior to amplification, such as the

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methods suggested by Pollet et al and Feix et al," whereas the Attachment states "the combined teachings of Pollet et al and Feix et al do not teach a method having the advantages disclosed and claimed by applicants, in which a target bound to a support that has been 'substantially separated' from a sample may be immediately subjected to *in vitro* amplification without a requirement for additional steps such as separation of target from the support." Ms. Fordis noted that the claimed invention encompasses multiple rounds of capture and amplification after release of target, and that she had believed that the statement regarding "additional steps....suggested by Pollet et al and Feix et al" in the Interview Summary referred to additional purification steps such as dialysis, not to steps of target capture and release. The examiner indicated that she had reviewed the specification, the Interview Summary and the Attachment, and discussed Ms. Fordis' concerns with Primary Examiner Carla Myers. The examiner agreed with Ms. Fordis that the claims encompass methods in which separation from the support occurs, and indicated that her statement in the Attachment re: "additional steps such as separation of target from the support" was therefore inaccurate. Rather, as discussed in the Interview of 4/2/02 and as noted in the Interview Summary of paper no. 35, the claims do not encompass methods requiring the additional steps of target purification prior to amplification suggested by Pollet et al and Feix et al such as, e.g., dialysis.



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Fax Cover Sheet

Date: 08 May 2002

To: Jean Fordis

From: Diana B. Johannsen

Application/Control Number: 09/533,906

Art Unit: 1634

Fax No.: 202/408-4400

Phone No.: 703/305-0761

Voice No.: 650/849-6607

Return Fax No.: 703/872-9306

Re:

CC:

☐ **Urgent** ☐ **For Review** ☐ **For Comment** ☐ **For Reply** ☐ **Per Your Request**

Comments:
Interview Summary.

Number of pages 5 **including this page**

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